

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

THE HIPSAVER COMPANY, INC.,

Plaintiff,

V.

J.T. POSEY COMPANY,

Defendant.

Civil Action No. 05-10917 PBS

DECLARATION OF VICTORIA GAY LEWIS

I, Victoria Gay Lewis, declare:

1. I am a Product Manager for J.T. Posey Company (“Posey”). I have held this position at Posey since April 1999. As Product Manager, I am responsible for certain categories of Posey products. The categories of products under my responsibility are products that we categorize as “Care Alternatives”, which include Fall Management and Fall Prevention products such as Hipsters, Floor Cushions, Fall Monitors and Sensors. The facts recited in this declaration are within my personal knowledge and if called as a witness I could and would testify thereto. I submit this declaration in support of Defendant J.T. Posey Company’s (“Posey”) Motion to Dismiss The HipSaver Company’s (“HipSaver”) Complaint Under Fed. R. Civ. P. Rule 12(b)(6), For More Definite Statement Under Rule 12(e), Or, Alternatively, for Summary Judgment Under Rule 56 (“Posey’s Motion”).

2. My responsibilities at Posey include, among other things, development and introduction of new products, evaluation and implementation of product enhancements, and assistance in support, management and promotion of existing products.

3. I have been involved in the development of the Posey Hipster products, which are designed to protect the hip in elderly patients and to reduce the likelihood of a hip fracture in the event of a fall.

4. In 2001, Posey engaged an independent laboratory, Garwood Laboratories, Inc. located in Los Angeles, California, to conduct tests to determine the relative effectiveness of various foam pads that Posey was considering inserting into a hip protector (the "Impact Study").

5. Beginning in 2002, Posey created and disseminated various advertising materials that made reference to the results of the Impact Study. True and correct copies of three advertisements that made reference to the Impact Study and that were distributed nationwide are attached hereto as Exhibit "D", "E" and "F".

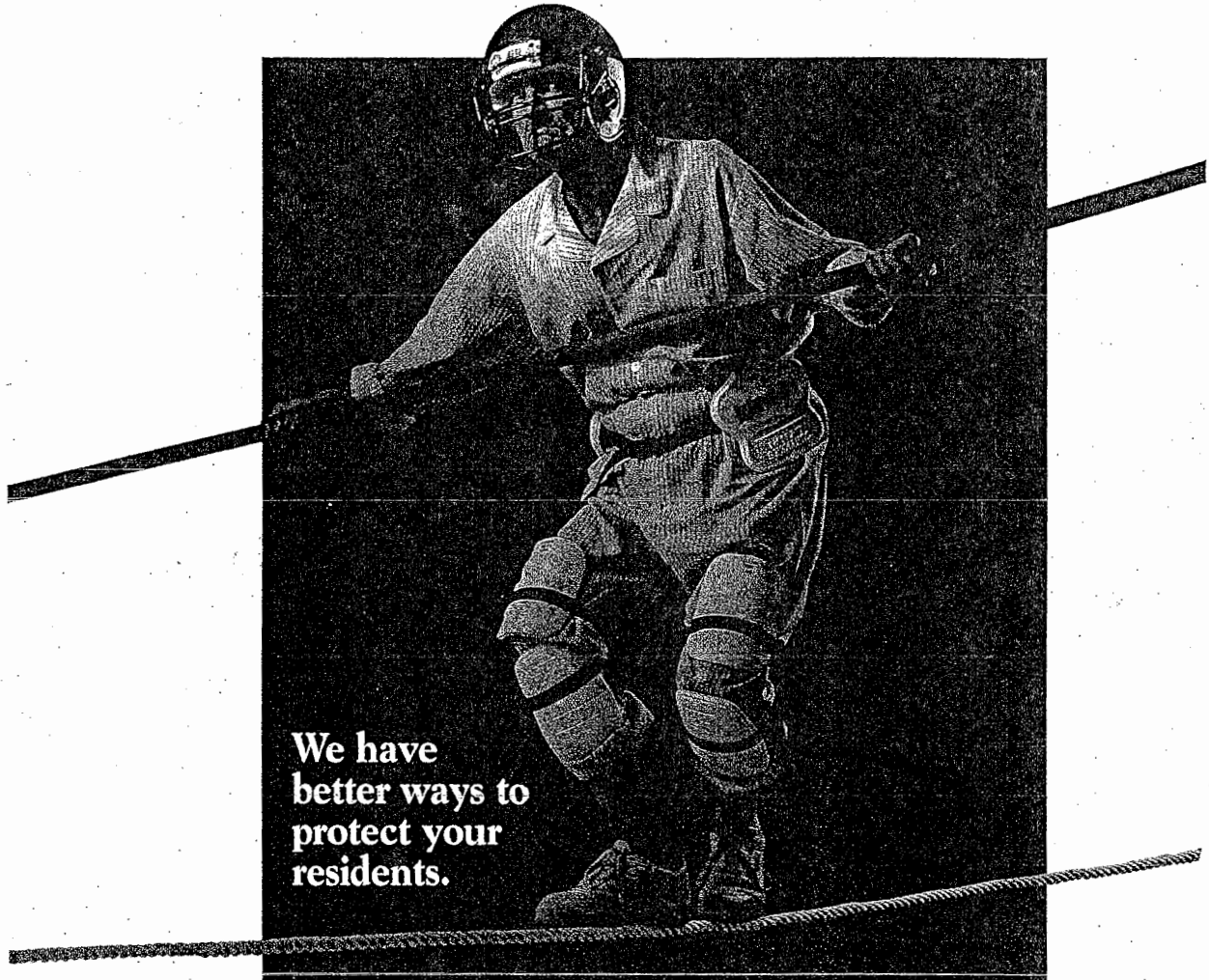
6. Exhibit "D" was disseminated to various hospitals and other elder care facilities beginning at least as early as September 17, 2002. Exhibit "E" was disseminated to various hospitals and other elder care facilities beginning at least as early as, December 13, 2002. Exhibit "F" was disseminated to various hospitals and other elder care facilities beginning at least as early as June 20, 2003. The advertisement dated January 24, 2005, which is attached to the May 18, 2005 letter from HipSaver's counsel to Posey attached to Posey's Motion as Exhibit B, is created from and based on the advertisements attached hereto as Exhibits "D", "E" and "F."

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct and that this declaration was executed this 16th day of June, 2005 at Arcadia, California.

/s/ Victoria Gay Lewis
Victoria Gay Lewis

EXHIBIT "D"

FOR SOME RESIDENTS, EVERY FALL IS A BIG ONE.

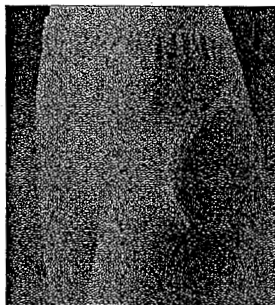


We have
better ways to
protect your
residents.

POSEY HIPSTERS

It's a long way down for residents at risk of injury from falls. You can greatly reduce that risk with Posey Hipsters. High energy-absorbing, viscoelastic foam pads built into Hipsters increase the odds of surviving a fall uninjured. They are comfortable and slim enough to be virtually undetectable beneath clothing.

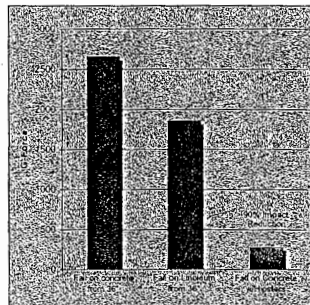
By offering increased protection, Hipsters relieve residents' anxiety about falling and enhance their quality of life.



IMPACT REDUCED BY 90%

An independent laboratory study simulated the fall of a 120-lb object onto concrete from a height of 36". Posey Hipster pads reduced the impact force by 90%.

Data on file at J.T. Posey Company.



SPECIAL OFFER:
30-day no-obligation
free trial.

Test the new Hipster for
yourself at no charge.
Call or visit our Website
today to start your free trial.

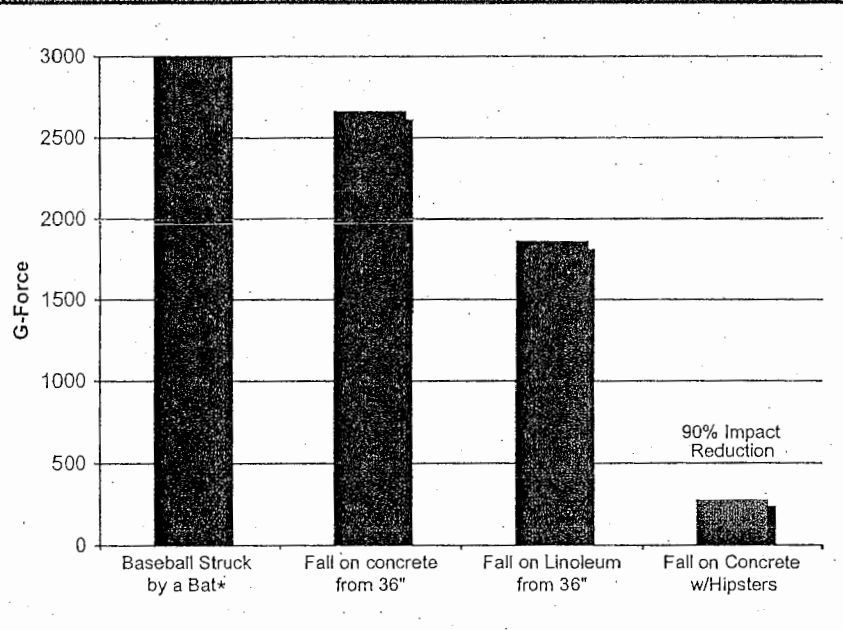
POSEY CA
Care Alternatives Division

Fall Protection That Fits

1-800-44-POSEY

www.posey.com

Posey Hipsters Proven Effective in Laboratory Test



Testing was conducted by Garwood Laboratories, July 2001. Data on file at J.T. Posey Company.

A non-dependent laboratory study was conducted to determine the most effective commercially available impact absorbing material as of July 2001. A test was created that would simulate a fall causing direct impact to the greater trochanter. In this study, a weight was released as a guided drop to simulate a 120 lb. subject falling from a height of 36" (the estimated height of the hip above the floor for a typical nursing home resident). The baseline measurement of impact force was determined to be a fall directly onto concrete. The G-Force of a fall under this scenario was 2,650 G, and for purposes of comparison is just slightly less impact force than a baseball being struck by a bat*. In the extreme to the low profile Posey Hipster, reduced the impact force by 90% and showed excellent impact energy absorption.

*Source: www.mjs.org

FALL MANAGEMENT - FALL PROTECTION



CLINICAL REFERENCES SUPPORTING THE USE OF EXTERNAL HIP PROTECTORS

"If hip protectors are worn, the doubling of hip fractures, expected in the next few decades because of aging of the population might not turn out to be reality."

Lyritis, G. T. B., Petersen, M. M., Lund, B. (1996, January 2). Effect of external hip protectors on hip fracture. *Lancet*, (347).

"With improved compliance, external hip protectors should be an effective prophylactic against hip fractures."

Elkman, A., Mallmin, H., Michaelsson, K., Ljunghall, S. (1997, August 23). External hip protectors to prevent osteoporotic hip fractures. *Lancet*, (350).

"Only 41 persons need to use the hip protector for one year for 8 persons for 5 years in order for one fracture"

EXHIBIT "E"

POSEY HIPSTERS PROTECT AGAINST INJURY FROM FALLS



It's a long way down for residents at risk of injury from falls. You can greatly reduce that risk with Posey Hipsters. The Hipsters' high energy-absorbing foam pads are positioned precisely over the hip bones, increasing the odds of surviving a fall uninjured. The Hipsters are comfortable and slim enough to be virtually undetectable under clothing. By offering increased protection, Hipsters relieve residents' anxiety about falling and enhance their quality of life.

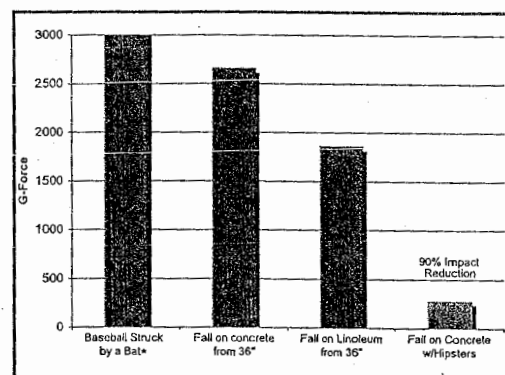
- High impact-absorbing viscoelastic pads protect hip bones against injury from falls
- Soft, comfortable pads improve compliance versus hard-shelled products
- Washable to CDC standards for soiled linen without removing the pads
- 100% latex-free
- Five sizes for correct fit
- Discreet, low-profile pads are virtually undetectable under clothing



*Low Profile -
All styles fit
discreetly
under men's
and women's
clothing.*

PROVEN IMPACT REDUCTION

In an independent laboratory, simulating a fall from a height of 36 inches, the Hipsters reduced the impact force by over 90%.



Testing was conducted by Garwood Laboratories, July 2001. Data on file at J.T. Posey Company

POSEY CA
Care Alternatives Division

Special offer: 30-day no-risk free trial.
Test the Posey Hipsters for yourself with no obligation to buy.

Clinical References Supporting the Use of Hip Protectors

Title: **External Hip Protectors to Prevent Osteoporotic Hip Fractures**
 Author: A. Ekman, H. Mallmin, K. Michaëlsson, S. Ljunghall
 Publication: The Lancet, volume 350, August 23, 1997

Study Objectives: Ekman and colleagues conducted a controlled study on the use of hip protection to prevent hip fractures. One expectation was to either confirm or disprove the 1993 reported findings of J.B. Lauritzen and colleagues in "Effect of external hip protectors on hip fractures."

Results: The use of hip protectors as preventative treatment for hip fractures was validated. "Our study confirms a reduced risk for hip fractures of the same magnitude as the previous report."

Recommendations: "With improved compliance, external hip protectors should be an effective prophylactic against hip fractures."

Title: **Prevention Of Hip Fracture in Elderly People**
 Author: Pekka Kannus, M.D., Ph.D., et al
 Publication: The New England Journal of Medicine, Vol. 343, No. 21, November 21, 2000

Study Objectives: The purpose of this study was "to determine whether an external hip protector would be effective in preventing hip fractures among elderly adults." The study population was comprised of elderly adults from 22 community based health-care centers in Finland; a treatment group of 653 and a control group of 1,148 participants.

Results: The degree of compliance with the hip protector was $48 \pm 29\%$. The hip protector group suffered 13 hip fractures, 9 of which occurred while not wearing the hip protector, compared to 67 hip fractures in the control group.

Recommendations: "We conclude that the risk of hip fractures can be reduced in frail elderly adults through the use of an anatomically designed external hip protector. Only 41 persons need to use the hip protector for one year (or 8 persons, for five years) in order for one fracture to be prevented."

Please detach and fax to 1-800-767-3933, or call us at 1-800-44-POSEY to start your trial

yes!

I want to take advantage of your 30-day trial offer. Please have a representative call me to discuss Posey Hipsters.



Name _____
 Title _____
 Institution _____
 Address _____
 City _____ State _____ Zip _____
 Telephone () _____ Best time to call _____ am _____ pm

Fax or mail to:



J.T. Posey Company
 Attn: Marketing Dept.
 5635 Peck Road
 Arcadia, CA 91006-0020
 Fax 800-767-3933

EXHIBIT "F"



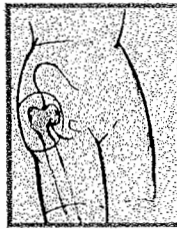
Posey® EZ On Hipsters™

In 1996, hospital admissions for hip fractures among people aged 65 and older totaled 340,000 and is expected to exceed 500,000 with a projected annual cost of \$240 billion by the year 2040.¹ Tragically, half of all older adults hospitalized for hip fractures cannot return home or live independently after their injury and about one quarter will die within one year due to the fracture or related complications.²

Several studies have documented the efficacy of external hip protectors in preventing hip fractures. These same studies also point out that patient compliance is a driving factor in product effectiveness. Posey Hipsters feature impact absorbing, soft foam pads over the critical fracture area to help minimize potential damage, including hip fractures that can occur from a fall. The low profile pads allow the Hipsters to be discreetly worn under clothing. These soft pads offer greater comfort when compared to hard shell style hip protectors. Patient comfort, coupled with the low profile design, helps increase patient compliance.

The EZ On Hipsters are applied around the waist and lower thigh using the hook-and-loop attachments, and allow the patients to wear their own undergarments. The mesh material is water permeable, allowing the EZ On Hipsters to be worn during bathing.

EZ On Hipsters feature removable pads. Although the pads are removable, the Hipsters can be laundered with the pads in place. Removing the pads prior to laundering will help prolong the life of the product.



While no product can provide complete protection from hip fractures, Posey Hipsters will help to minimize the potential for damage that can occur from a fall.

#6019 EZ On Hipsters

#6008 Replacement Pads, 1 pair

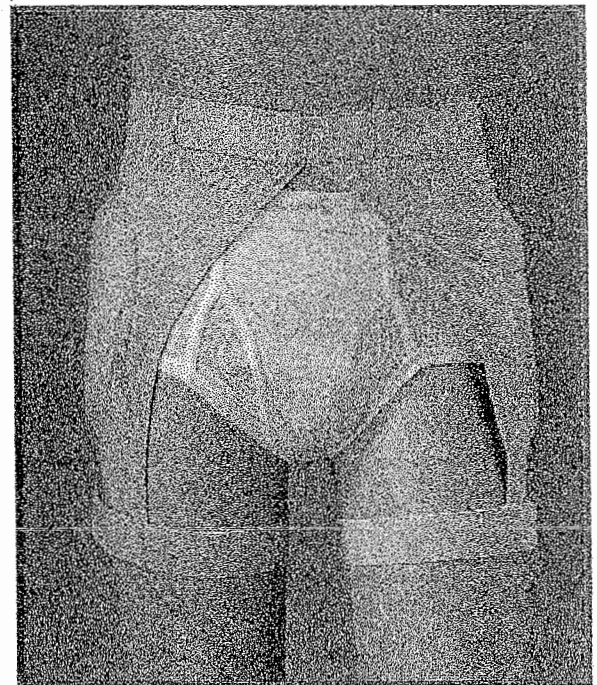
Application Instructions

1. Unfasten the hook and loop at the waist and thighs.
2. Wrap the garment around your waist. The labels should be oriented towards the back and on the inside of the waistband.
3. Fasten the hook and loop at the front of your waist. The waistband should be securely fastened to allow minimal shifting of the garment but should not feel tight or restrictive.
4. Pull the left panel taut over the left hip and thigh. The pad should be positioned directly over the hip joint.
5. Secure around the lower thigh using the hook and loop attachment. The elastic band should be tight enough to prevent the pad from sliding out of place without restricting circulation.
6. Repeat steps 4 and 5 on right side.

Laundering Instructions

Posey Hipsters may be washed according to CDC standards (see symbols below). Using the lower temperature washing and drying cycle for non-contaminated linen will prolong product life.

- If hook and loop does not adhere, it is most likely due to a collection of lint. Clean hook by brushing with a stiff brush.
- If pads are removed, wipe clean with mild, liquid disinfectant before replacing in the pants.



#6019

Sizing Chart

Size	Waist Measurement	Hip Measurement
S	28" - 30"	35" - 37"
M	32" - 34"	39" - 41"
L	36" - 38"	43" - 45"
XL	40" - 42"	47" - 49"
XXL	44" - 48"	51" - 53"

WARNING

Due to the random possibilities of fall characteristics, the Posey Company makes no guarantee, express or implied, that the user is protected from hip trauma. The skin under the pants should be assessed regularly and Hipsters should be changed and washed after each incontinent episode to prevent skin breakdown.

WARNING

- Posey Hipsters contain foam pads that are sealed in a pouch to protect the foam.
- If the pouch is cut or the seal is broken in laundering, moisture will enter the pouch and compromise the impact absorption quality of the foam.
- Test pouch and foam integrity by squeezing the pad in one fist, forcing the air to one end, resulting in an air bubble.
- If you hear or feel air or liquid escaping, or the foam feels soft and spongy, the pouch is damaged.
- Remove the damaged pouch and replace with a new one.

¹ Centers for Disease Control and Prevention, 3 Aug 2001, www.cdc.gov. ² Rubenstein, Laurence, M.D., M.P.H. (2000) Hip Protectors - A Breakthrough in Fracture Prevention. The New England Journal of Medicine.



Clinical References Supporting the Use of Hip Protectors

Title: *External Hip Protectors to Prevent Osteoporotic Hip Fractures*
 Author: A. Ekman, H. Mallmin, K. Michaëlsson, S. Ljunghall
 Publication: The Lancet, volume 350, August 23, 1997

Study Objectives: Ekman and colleagues conducted a controlled study on the use of hip protection to prevent hip fractures. One expectation was to either confirm or disprove the 1993 reported findings of J.B. Lauritzen and colleagues in "Effect of external hip protectors on hip fractures."

Results: The use of hip protectors as preventative treatment for hip fractures was validated. "Our study confirms a reduced risk for hip fractures of the same magnitude as the previous report."

Recommendations: "With improved compliance, external hip protectors should be an effective prophylactic against hip fractures."

Title: *Prevention Of Hip Fracture in Elderly People*
 Author: Pekka Kannus, M.D., Ph.D., et al
 Publication: The New England Journal of Medicine, Vol. 343, No. 21, November 21, 2000

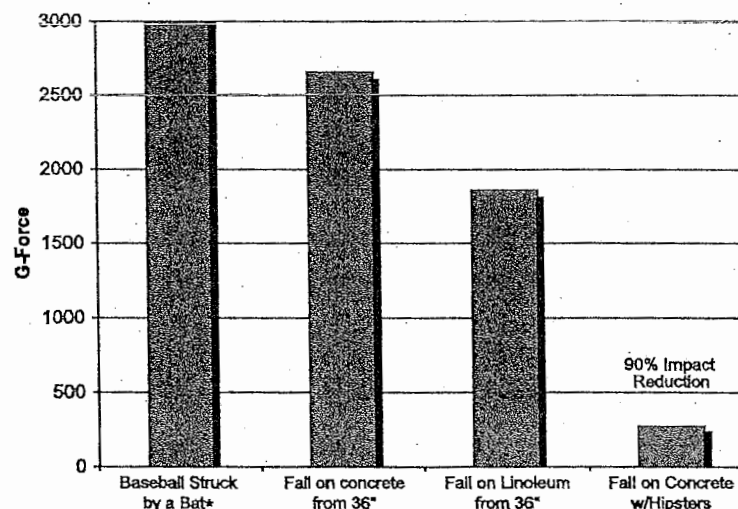
Study Objectives: The purpose of this study was "to determine whether an external hip protector would be effective in preventing hip fractures among elderly adults." The study population was comprised of elderly adults from 22 community based health-care centers in Finland; a treatment group of 653 and a control group of 1,148 participants.

Results: The degree of compliance with the hip protector was $48 \pm 29\%$. The hip protector group suffered 13 hip fractures, 9 of which occurred while not wearing the hip protector, compared to 67 hip fractures in the control group.

Recommendations: "We conclude that the risk of hip fractures can be reduced in frail elderly adults through the use of an anatomically designed external hip protector. Only 41 persons need to use the hip protector for one year (or 8 persons for five years) in order for one fracture to be prevented."

Posey Hipsters Proven Effective in Laboratory Test

An independent laboratory study was conducted to determine the most effective impact absorbing material as of July 2001. A test was created that would simulate a fall causing direct impact to the greater trochanter. In this study, a weight was released in a guided drop to simulate a 120lb subject falling from a height of 36", or the estimated height of the hip above the floor for a typical nursing home resident. The baseline measurement of impact force was determined to be a fall directly onto concrete. The G-Force of a fall under this scenario was 2,660G's and, for purposes of comparison, is just slightly less impact force than that of a baseball being struck by a bat. In this extreme test, the low profile Posey Hipster reduced the impact force by 90% and showed excellent impact energy absorption.



Testing was conducted by Garwood Laboratories, July 2001. Data on file at J.T. Posey Company
 *Source: www.madscl.org